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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,126	06/15/2001	Assaf Govari	BIO-136	8637

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NEW BRUNSWICK, NJ 08933-7003

EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/882,126

Applicant(s)

GOVARI, ASSAF

Examiner

Fangemonique Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION

- 1) This Office Action is responsive to the Amendment filed June 12, 2006. Claims 1-21 are pending in the application.

Claim Rejections - 35 USC § 102

- 2) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 3) Claims 1-2, 4-5, and 9-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischman et al. (U.S. Patent Number US 6,241,724 B1)

In regard to claims 1-2, 4-5, and 9-12, Fleischman et al. disclose a method for measuring temperature at a site within a patient during a medical procedure. The method comprises providing a medical device (20) having a position sensor (12/136), which provide for the assessment of electrode positioning at the site (col.2, lines 9-36). The medical device (20) of the Fleischman et al. patent is placed within the patient and the position sensor (12/136) is positioned at the site (col. 5, lines 4-10, 56-67). Signals provided by the position sensor (12/136) are sent to a location system (142) that determines the position of the position sensor (col. 11, lines 15-48). The device further includes temperature-sensing devices, which provide a temperature

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measurement signal of the environment to the position sensor (12/136). The medical device is further used to measure the voltage at the tip (140) of the position sensor (12/136). An impedance measurement is determined based on the temperature measurement signal and the voltage. An algorithm performed by the control system (200) of the Fleischman et al. device is also capable of determining the temperature value based on the resistance value (col. 6, lines 8-52). The control system has signal processing capabilities, which are employed to measure the resistance value and the temperature value at the site. The Fleischman et al. patent further includes using a signal processor for measuring the voltage at the position sensor (col. 12, lines 1-16). The device of the Fleischman et al. patent includes a module (23), which is an external source for delivery of RF energy applied at the site within the patient (col. 4, lines 65-67; col. 5; col. 6, lines 1-8). Fleischman et al. disclose performing an ablation procedure at the site with the medical device (col. 2, lines 9-17).

In regard to claims 13-15, Fleischman et al. disclose a method for adjusting for temperature sensitivity of a medical device having a position sensor (12/136). The method disclosed by Fleischman et al. comprises the steps of providing a medical device having a position sensor (12/136). The medical device is used to measure voltage at the tip (140) of the position sensor (136) and is capable of determining a resistance value from the measured voltage (col. 12, lines 1-16). Fleischman et al. further describe the medical device being capable of determining temperature value and temperature sensitivity at the position sensor based on the resistance value (col. 5, lines 47-67; col. 6 lines 1-67; col. 7, lines 1-5). Based on the temperature information gathered, the control system of the medical device modifies the location information (col. 10, lines 27-37). Additionally, the method according to Fleischman comprises adjusting position

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and orientation coordinates from the position sensor based on the sensitivity (col.11, lines3-67; col. 12).

Claim Rejections - 35 USC § 103

- 4) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 5) Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman et al. (U.S. Patent Number 6,241,724) in view of Goldin et al. (U.S. Patent Number 6,569,160).

In regard to claims 6-8, Fleischman et al. disclose a method for measuring temperature at a site within a patient during a medical procedure which includes the features of the Applicant's invention as described above. Fleischman et al. further describe the medical device being capable of determining a temperature value and temperature sensitivity at the orientation sensing mechanism based on the resistance value (col. 5, lines 47-67; col. 6 lines 1-67; col. 7, lines 1-5). The device of the Fleischman et al. patent includes a module (23), which is an external source for delivery of RF energy applied at the site within the patient (col. 4, lines 65-67; col. 5; col. 6, lines 1-8). Fleischman et al. disclose performing an ablation procedure at the site with the medical device (col. 2, lines 9-17). Fleischman et al. does not disclose the use of an AC generator signal. Goldin et al. disclose a system and method for detecting electrode tissue-contact, which comprises a medical catheter device having a location sensor. The medical device of the Goldin et al. patent is used to perform ablation procedures. The device includes a signal generator,

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which delivers an AC signal to the distal tip of the device. Operation of the device further includes transforming the AC signal into a DC signal upon utilizing a synchronous detector. The generator signal of the Goldin device is capable of operating at 3KHz with the temperature measurement signal at 4Hkz. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to include an AC generator and synchronous detector system, similar to that disclosed by Goldin et al., to deliver an AC signal to a medical device used to perform ablation procedures, similar to Fleischman's ablation apparatus, as a way to provide a means for decreasing the sensitivity of the medical device to external noise (col. 12, lines 53-67; col. 13, lines 1-25).

- 6) Claims 3 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman et al. (U.S. Patent Number 6,241,724) in view of Douglass et al. (U.S. Patent Number 5,638,418).

In regard to claims 3 and 16-21, Fleischman et al. disclose a method for measuring temperature at a site within a patient during a medical procedure. The method comprises providing a medical device having at least two electrode segments and a position sensor (12/136), which provide for the assessment of electrode positioning at the site (col.2, lines 9-36). The medical device of the Fleischman et al. patent is placed within the patient and the position sensor (12/136) is positioned at the site. The device further includes temperature-sensing devices, which provide a temperature measurement signal of the environment to the position sensor (12/136). The medical device is further used to measure the voltage at the tip (140) of the position sensor (12/136). An impedance measurement is determined based on the temperature measurement signal and the voltage. An algorithm performed by the control system (200) of the Fleischman et

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al. device is also capable of determining the temperature value based on the resistance value (col. 6, lines 8-52). The control system has signal processing capabilities, which are employed to measure the resistance value and the temperature value at the site. A profile of resistance and sensitivity versus temperature is developed from the collected information (col. 6, lines 4-67). Fleischman et al. disclose performing an ablation procedure at the site based on the resistance and sensitivity profile information (col. 2, lines 9-17). Fleischman et al. does not disclose providing a resistance drift factor to the resistance value or sensitivity drift factor to the temperature value when executing the algorithm. Douglass et al. disclose a system and method that is used to detect temperature. The method includes including an error term to simulate possible drift of resistance values. The system of the Douglass et al. patent uses the resistance drift coefficient during its processing step, which is stored by a memory device of the system. Douglass et al. further disclose a temperature coefficient introduced to adjust the temperature measurement according to the temperature sensitivity of the device in operation. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to apply correction factors, similar to those disclosed by Douglass et al., to an algorithm used to measure temperature similar to the one used by Fleischman et al. in order to improve the accuracy of the calculated measurement and reduce sources of variability.

Response to Arguments

- 7) Applicant argues that the Fleischman et al. reference does not have a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor. Examiner respectfully disagrees. In a broad reasonable interpretation, the distal end

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of the catheter disclosed by Fleischman et al. may be interpreted as a position sensor. The claims only require that the position sensor provide signals that are used to determine position and/or orientation coordinates. The Examiner notes the claim does not expressly require determination of position coordinates due to the alternative language used in claim. The Examiner further notes that upon determination of the coordinates, they do not appear to be used further in the claimed method. Signals provided by the Fleischman et al. position sensor (12/136) are sent to a location system (142) that determines position of the sensor (i.e. which electrodes/temperature sensors are in contact with tissue). Therefore, the distal end of the catheter disclosed by Fleischman et al. meets this limitation. Applicant's arguments regarding claims 1-2, 4-5 and 9-15 with respect to the Fleischman et al. reference have been fully considered but they are not persuasive. The rejection stands.

- 8) Applicant states the Goldin et al. reference is directed to a system and method for detecting electrode-tissue contact which discloses use of a position sensor, however does not suggest the position sensor to be used in conjunction with a device for measuring temperature at a within a patient. Examiner respectfully disagrees. The Fleischman et al. apparatus is a medical device, which may be used for tissue ablation procedures. The Fleischman et al. device detects temperature at a site within a body of patient during operation of the device. The apparatus disclosed by Goldin et al. is also a tissue ablation device, similar to that of Fleischman, which includes an AC generator and a synchronous detector system. In order to maintain the functionality of the Fleischman et al. device while decreasing the sensitivity of the device to external noise, one is motivated to combine Fleischman with Goldin et al. Applicant's arguments filed December 20, 2005 regarding claims 6-8 with respect to the

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Goldin et al. reference have been fully considered but they are not persuasive. The rejection stands.

- 9) Applicant's arguments with respect to claims 3 and 16-21 have been considered but are not persuasive. Applicant argues that the combined Fleischman et al. and Douglass et al. references do not meet the limitations of the method disclosed by Applicant. As expressed above, Examiner respectfully disagrees with the Applicant. The combined references meet the limitations of the Applicant's invention of providing a medical device, which determines the position and/or orientation of the device at the site. The combined references further provide a device used to determine the temperature at the site with a temperature value sensitivity drift factor employed in the algorithm to improve the accuracy of the calculated temperature measurement. Therefore, the rejection based on the combined Fleischman et al. and Douglass et al. references is proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 7am - 3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FS

A handwritten signature in black ink, appearing to read "Max Hindenburg", is located in the bottom right corner of the page.